

K082308

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DEC 09 2008

**Submitter:** Edwards Lifesciences LLC  
One Edwards Way  
Irvine, CA 92614-5686

**Contact Person:** Jason Smith, Project Manager, Regulatory Affairs

**Date Prepared:** December 8, 2008

**Trade name:** *Vigileo* APCO/Oximetry Monitor

**Classification Name:** Cardiac Output/Oximeter Computer  
Single-Function, Preprogrammed Diagnostic Computer  
(21 CFR 870.1435)

**Predicate Device:** *Vigileo* APCO/Oximetry Monitor: K062134, cleared August 22, 2006

**Device Description:** The *Vigileo* APCO/Oximetry Monitor is a microprocessor-based instrument which, when connected to a FloTrac sensor, continuously measures arterial pressure cardiac output (APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry) in adults or pediatrics. The monitor also calculates other derived parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, systemic vascular resistance, systemic vascular resistance, delivered oxygen, delivered oxygen index, and pulse oximetry saturation.

**Intended Use:** The *Vigileo* APCO/Oximetry Monitor is intended to continuously measure hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics.

**Comparative Analysis:** The *Vigileo* APCO/Oximetry Monitor has been demonstrated to be as safe and effective as the predicate device for its intended use.

**Functional/Safety Testing:** The *Vigileo* APCO/Oximetry Monitor has successfully undergone functional testing demonstrating equivalence to the predicate device.

**Conclusion:** The *Vigileo* APCO/Oximetry Monitor is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 09 2008

Mr. Jason Smith  
Project Manager, Regulatory Affairs  
Edwards Lifesciences, LLC  
One Edwards Way  
Irvine, CA 92614

Re: K082308  
Trade/Device Name: Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor  
Regulation Number: 21 CFR 870.1435  
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer  
Regulatory Class: Class II (Two)  
Product Code: DXG and DQE  
Dated: November 20, 2008  
Received: November 21, 2008

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

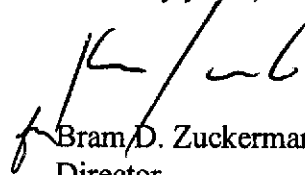
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Appendix A: Indications for Use Statement

510(k) Number (if known):

Device Name: Vigileo APCO/Oximetry Monitor

**Indications for Use:**

The Vigileo APCO/Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics.

Prescription Use   X   AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**

#### Division of Cardiovascular Devices

510(k) Number 1K082308

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